

are not subject to the limitations and standards of this part.

(2) Non-contact cooling water, utility wastewaters, general site surface runoff, groundwater (e.g., contaminated groundwaters from on-site or off-site groundwater remediation projects), and other non-process water generated on site. Discharges of such waters and wastewaters are not subject to the limitations and standards of this part.

(k) The term *non-conventional pollutants* means parameters that are neither conventional pollutants (40 CFR 401.16), nor “toxic” pollutants (40 CFR 401.15).

(l) The term *surrogate pollutant* means a regulated parameter that, for the purpose of compliance monitoring, is allowed to serve as a surrogate for a group of specific regulated parameters. Plants would be allowed to monitor for a surrogate pollutant(s), when the other parameters for which it stands are receiving the same degree of treatment as the surrogate pollutant(s) and all of the parameters discharged are in the same treatability class(es) as their respective surrogate pollutant(s). Treatability classes have been identified in Appendix A to this part for both steam stripping and biological treatment technologies, which are the respective technology bases for PSES/PSNS and BAT/NSPS limitations controlling the discharge of regulated organic parameters.

(m) The term *xylenes* means a combination of the three isomers: o-xylene, p-xylene, and m-xylene.

(n) The abbreviation Mg/L means milligrams per liter or parts per million (ppm).

[63 FR 50425, Sept. 21, 1998; 64 FR 48104, Sept. 2, 1999]

#### § 439.2 Monitoring requirements.

Unless otherwise noted, self-monitoring will be conducted at the final effluent discharge point.

#### § 439.3 General pretreatment standards.

Any source subject to this part that introduces process wastewater pollutants into a publicly owned treatment works (POTW) must comply with 40 CFR part 403.

[63 FR 50425, Sept. 21, 1998]

#### § 439.4 Monitoring requirements.

Permit limits and compliance monitoring are required for each regulated pollutant generated or used at a pharmaceutical manufacturing facility, except where the regulated pollutant is monitored as a surrogate parameter. Permit limits and compliance monitoring are not required for regulated pollutants that are neither used nor generated at the facility. Except for cyanide, for which an alternate monitoring requirement is established in subparts A and C of this part a determination that regulated pollutants are neither used nor generated should be based on a review of all raw materials in use, and an assessment of the process chemistry, products and by-products resulting from each of the manufacturing processes. This determination along with recommendation of any surrogate must be submitted with permit applications for approval by the permitting authority, and reconfirmed by an annual chemical analysis of wastewater from each monitoring location, and the measurement of a non-detect value for each regulated pollutant or its surrogate. Permits shall specify that such determinations will be maintained in the facility's permit records with their discharge monitoring reports and will be available to regulatory authorities upon request.

[63 FR 50425, Sept. 21, 1998]

### Subpart A—Fermentation Products Subcategory

#### § 439.10 Applicability.

This subpart applies to discharges of process wastewater resulting from the manufacture of pharmaceutical products by fermentation.

[63 FR 50426, Sept. 21, 1998]

#### § 439.11 Specialized definitions.

For the purpose of this subpart:

(a) The term *fermentation* means process operations that utilize a chemical change induced by a living organism or enzyme, specifically, bacteria, or the microorganisms occurring in unicellular plants such as yeast, molds, or fungi to produce a specified product.